DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 14, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to Warning Letter SEA 02 – 11

Mr. Kohji Kamiya, President
Kamiya Biomedical Company
910 Industry Drive
Seattle, Washington 98188-3412

WARNING LETTER

Dear Mr. Kamiya:

During an inspection of your establishment on September 12-14 and 17-18, 2001, Investigator Brenda L. Reihing determined that your firm repackages, labels, stores, and distributes immunoassay reagents, calibrator sets, and control sets. These are defined as devices by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The recent inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows.

1. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100 (attached)].

2. Failure to appoint and document a member of management with executive responsibility who shall have established authority over and responsibility for: (1) ensuring that quality system requirements are effectively established and effectively maintained; and, (2) reporting on the performance of the quality system to management with executive responsibility for review [21 CFR 820.20 (attached)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigation and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to: seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the U.S. Food and Drug Administration, 22201 23rd Drive SE, Bothell, WA 98021-4421, Attention: Thomas S. Piekarski, Compliance Officer.

Sincerely,

Charles M. Breen
District Director

Enclosure:
21 CFR 820.100, Corrective and preventive action
21 CFR 820.20, Management responsibility